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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,625	02/07/2000	WINOK DEBYSER	VANME31.001APC	7510

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/403,625

Applicant(s)
Debyser et al.

Examiner
Christian L. Fronda

Art Unit
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-13 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. In the AMENDMENT dated May 6, 2002 (Paper No. 10), Applicants have amended claims 6-13.
2. Claims 6-13 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 6-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed May 6, 2002 (Paper No. 10) have been fully considered but they are not persuasive. Applicants' position is that the specification provides an adequate written description of claimed protein to enable the skilled artisan to recognize that Applicants were in possession of the claimed invention. The Examiner disagrees with Applicants' position.

The specification only describes a xylanase inhibitor which is a water-soluble, alkaline protein having two subunits with a partial N-terminal amino acid sequence of SEQ ID NO: 1 and SEQ ID NO: 2, a molecular weight of 40-43 kDa, and pI of greater than about 7.0. The claims are directed to (1) any proteinic or glycoprotein xylanase inhibitor having any structure or amino acid sequence and (2) any xylanase inhibitor comprising any amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these proteins by any identifying structural characteristics or properties for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Amending the claims to recite that the claimed inhibitor is a water-soluble, alkaline protein

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having two subunits with an amino acid sequence of SEQ ID NO: 1 and SEQ ID NO: 2, the molecular weight of 40-43 kDa, and pI of greater than about 7.0 may overcome the rejection.

5. Claims 6-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for xylanase inhibitor which is a water-soluble, alkaline protein having two subunits with a partial N-terminal amino acid sequence of SEQ ID NO: 1 and SEQ ID NO: 2, a molecular weight of 40-43 kDa, and pI of greater than about 7.0, does not reasonably provide enablement for (1) any proteinic or glycoprotein xylanase inhibitor having any structure or amino acid sequence, (2) any proteinic or glycoprotein xylanase inhibitor comprising any amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2, or (3) any proteinic or glycoprotein xylanase inhibitor comprising the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments filed May 6, 2002 (Paper No. 10) have been fully considered but they are not persuasive. Applicants' position is that the specification provides adequate guidance for preparing extracts and using assays to screen for xylanase inhibitors such that one of skill in the art may practice the claimed invention using routine experimentation. The Examiner disagrees with Applicants' position.

The specification teaches a xylanase inhibitor which is a water-soluble, alkaline protein having two subunits with a partial N-terminal amino acid sequence of SEQ ID NO: 1 and SEQ ID NO: 2, a molecular weight of 40-43 kDa, and pI of greater than about 7.0. The nature and breadth of the claims encompass (1) any proteinic or glycoprotein xylanase inhibitor having any structure or amino acid sequence, (2) any proteinic or glycoprotein xylanase inhibitor comprising any amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2, or (3) any proteinic or glycoprotein xylanase inhibitor comprising the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2. Knowledge regarding the specific structure of any proteinic or glycoprotein xylanase inhibitor, any proteinic or glycoprotein xylanase inhibitor comprising any amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2, or any proteinic or glycoprotein xylanase inhibitor comprising the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2 is lacking. Furthermore, knowledge regarding the specific amino acid sequence of any proteinic or glycoprotein xylanase inhibitor comprising only SEQ ID NO: 1 or SEQ ID NO: 2, or the amino acid residues to substitute, delete, insert, or combinations thereof in SEQ ID NO: 1 or SEQ ID NO: 2 to make a protein or glycoprotein which is still able to inhibit xylanase enzyme activity and comprises an amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2 is lacking.

The amount of experimentation to make the claimed inventions is enormous. Such experimentation entails inserting, deleting, substituting, or combinations thereof amino acid

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residues in SEQ ID NO: 1 or SEQ ID NO: 2 and determining whether the protein or glycoprotein is still able to inhibit xylanase enzyme activity and has an amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2. Since routine experimentation does not include screening vast numbers of organisms for a specific organism which contains proteinic or glycoprotein xylanase inhibitor or inserting, deleting, or substituting amino acids in SEQ ID NO: 1 or SEQ ID NO: 2 and screening for proteins which still inhibit xylanase activity and comprises an amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific amino acid residues to change in SEQ ID NO: 1 or SEQ ID NO: 2 to make a protein which is still able to inhibit xylanase activity and comprises an amino acid sequence that is at least 70% or 85% identical to SEQ ID NO: 1 or SEQ ID NO: 2. Without such a guidance, the experimentation left to those skilled in the art is undue.

Conclusion

6. No claim is allowed.

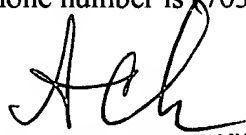
7. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

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